

## **Rapid Response Characterization of New and Manipulated Tobacco Products**

Toxicity Testing of New and Manipulated Tobacco Products (Project 1)

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### **Abstract:**

In keeping with its mission to regulate tobacco products and protect the public health, the FDA Center for Tobacco Products (CTP) is committed to understanding how people use the myriad of diverse tobacco products available and the resulting exposure to toxins and addictive chemicals. As a strong first step to guide research efforts, the FDA CTP has established, based on peer-reviewed toxicological findings, a list of harmful and potentially harmful constituents to health (HPHCs) that may be inhaled, ingested, or absorbed as a result of tobacco product use. The HPHCs include carcinogens, respiratory, cardiovascular, reproductive, and developmental toxicants: all of these chemicals are known components of tobacco products. Starting in 2013, FDA-mandated reporting of the quantities of HPHCs in tobacco products will be required of the tobacco industry. Although tobacco product emissions and content are important components of a product's overall toxicity, user behavior and resulting human exposures are critical to understanding the difference in harm among the many tobacco product types and brands available. This project is designed to inform the FDA CTP's ongoing efforts to quantify actual human exposures, and identify and measure toxins that directly contribute to the risk of tobacco use-related disease. The scientific potency of traditional biomarker monitoring data hinges on the assumption that all of the study subjects faithfully and solely use the test product for prolonged periods. We know that most tobacco users, having the highest brand loyalty of all consumers, often do not comply with this requirement. The human behavior and exposure data that will be collected in support of this project are designed to enhance traditional biomarkers by providing a body of data that is not confounded by subject non-compliance, as these data are collected before and immediately after direct use of the tobacco products. Using a combination of human crossover trials and an established boost method paradigm, the relative exposures to HPHCs from new and manipulated tobacco products will be measured. These defensible objective data will be supported by a robust Quality Assurance/Quality Control program, and will be made available rapidly to FDA CTP and other collaborating Centers to inform tobacco regulation via a secure, privilege-based internet accessible database.